

PATENT COOPERATION TREATY

From the
INTERNATIONAL SEARCHING AUTHORITY

REC'D 21 FEB 2005

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To:

see form PCT/ISA/220

WRITTEN OPINION OF THE INTERNATIONAL SEARCHING AUTHORITY (PCT Rule 43bis.1)

Date of mailing

(day/month/year) see form PCT/ISA/210 (second sheet)

Applicant's or agent's file reference
see form PCT/ISA/220

FOR FURTHER ACTION

See paragraph 2 below

International application No.
PCT/US2004/015136

International filing date (day/month/year)
13.05.2004

Priority date (day/month/year)
27.06.2003

International Patent Classification (IPC) or both national classification and IPC
C07K14/705

Applicant
MONELL CHEMICAL SENSES CENTER

1. This opinion contains indications relating to the following items:

- ☒ Box No. I Basis of the opinion
- ☒ Box No. II Priority
- ☒ Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
- ☒ Box No. IV Lack of unity of invention
- ☒ Box No. V Reasoned statement under Rule 43bis.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
- ☐ Box No. VI Certain documents cited
- ☐ Box No. VII Certain defects in the international application
- ☐ Box No. VIII Certain observations on the international application

2. FURTHER ACTION

If a demand for international preliminary examination is made, this opinion will usually be considered to be a written opinion of the International Preliminary Examining Authority ("IPEA"). However, this does not apply where the applicant chooses an Authority other than this one to be the IPEA and the chosen IPEA has notified the International Bureau under Rule 66.1bis(b) that written opinions of this International Searching Authority will not be so considered.

If this opinion is, as provided above, considered to be a written opinion of the IPEA, the applicant is invited to submit to the IPEA a written reply together, where appropriate, with amendments, before the expiration of three months from the date of mailing of Form PCT/ISA/220 or before the expiration of 22 months from the priority date, whichever expires later.

For further options, see Form PCT/ISA/220.

3. For further details, see notes to Form PCT/ISA/220.

Name and mailing address of the ISA:



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**WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY**

International application No.
PCT/US2004/015136

Box No. I Basis of the opinion

1. With regard to the **language**, this opinion has been established on the basis of the international application in the language in which it was filed, unless otherwise indicated under this item.
 - ☐ This opinion has been established on the basis of a translation from the original language into the following language , which is the language of a translation furnished for the purposes of international search (under Rules 12.3 and 23.1(b)).
2. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application and necessary to the claimed invention, this opinion has been established on the basis of:
 - a. type of material:
 - ☒ a sequence listing
 - ☐ table(s) related to the sequence listing
 - b. format of material:
 - ☒ in written format
 - ☒ in computer readable form
 - c. time of filing/furnishing:
 - ☒ contained in the international application as filed.
 - ☒ filed together with the international application in computer readable form.
 - ☐ furnished subsequently to this Authority for the purposes of search.
3. ☐ In addition, in the case that more than one version or copy of a sequence listing and/or table relating thereto has been filed or furnished, the required statements that the information in the subsequent or additional copies is identical to that in the application as filed or does not go beyond the application as filed, as appropriate, were furnished.
4. Additional comments:

**WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY**

International application No.
PCT/US2004/015136

Box No. II Priority

1. ☒ The following document has not been furnished:

☒ copy of the earlier application whose priority has been claimed (Rule 43*bis*.1 and 66.7(a)).

☐ translation of the earlier application whose priority has been claimed (Rule 43*bis*.1 and 66.7(b)).

Consequently it has not been possible to consider the validity of the priority claim. This opinion has nevertheless been established on the assumption that the relevant date is the claimed priority date.

2. ☐ This opinion has been established as if no priority had been claimed due to the fact that the priority claim has been found invalid (Rules 43*bis*.1 and 64.1). Thus for the purposes of this opinion, the international filing date indicated above is considered to be the relevant date.

3. ☐ It has not been possible to consider the validity of the priority claim because a copy of the priority document was not available to the ISA at the time that the search was conducted (Rule 17.1). This opinion has nevertheless been established on the assumption that the relevant date is the claimed priority date.

4. Additional observations, if necessary:

**WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY**

International application No.
PCT/US2004/015136

Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability

The questions whether the claimed invention appears to be novel, to involve an inventive step (to be non obvious), or to be industrially applicable have not been examined in respect of:

- ☐ the entire international application,
- ☒ claims Nos. 1-3, 6-13, 15, 16, 18-38, 40-66, 68-72

because:

- ☐ the said international application, or the said claims Nos. relate to the following subject matter which does not require an international preliminary examination (*specify*):
- ☐ the description, claims or drawings (*indicate particular elements below*) or said claims Nos. are so unclear that no meaningful opinion could be formed (*specify*):
- ☐ the claims, or said claims Nos. are so inadequately supported by the description that no meaningful opinion could be formed.
- ☒ no international search report has been established for the whole application or for said claims Nos. 1-3, 6-13, 15, 16, 18-38, 40-66, 68-72
- ☐ the nucleotide and/or amino acid sequence listing does not comply with the standard provided for in Annex C of the Administrative Instructions in that:
 - the written form ☐ has not been furnished
 - ☐ does not comply with the standard
 - the computer readable form ☐ has not been furnished
 - ☐ does not comply with the standard
- ☐ the tables related to the nucleotide and/or amino acid sequence listing, if in computer readable form only, do not comply with the technical requirements provided for in Annex C-*bis* of the Administrative Instructions.
- ☐ See separate sheet for further details

**WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY**

International application No.
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Box No. IV Lack of unity of invention

1. ☒ In response to the invitation (Form PCT/ISA/206) to pay additional fees, the applicant has:
- ☐ paid additional fees.
 - ☐ paid additional fees under protest.
 - ☒ not paid additional fees.
2. ☐ This Authority found that the requirement of unity of invention is not complied with and chose not to invite the applicant to pay additional fees.
3. This Authority considers that the requirement of unity of invention in accordance with Rule 13.1, 13.2 and 13.3 is
- ☐ complied with
 - ☒ not complied with for the following reasons:
see separate sheet
4. Consequently, this report has been established in respect of the following parts of the international application:
- ☐ all parts.
 - ☒ the parts relating to claims Nos. 4-5, 14, 17, 39, 67 (completely); claims 1-3, 8-13, 20-38, 42-66, 70-72 (only partially)

Box No. V Reasoned statement under Rule 43bis.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Yes: Claims	-
	No: Claims	1-5, 8-14, 17, 20-39, 42-67, 70-72
Inventive step (IS)	Yes: Claims	-
	No: Claims	1-5, 8-14, 17, 20-39, 42-67, 70-72
Industrial applicability (IA)	Yes: Claims	1-5, 8-14, 17, 20-39, 42-67, 70-72
	No: Claims	-

2. Citations and explanations

see separate sheet

**WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING
AUTHORITY (SEPARATE SHEET)**

International application No.

PCT/US2004/015136

Reference is made to the following documents:

D1: WO 02/064631 A (ADLER JON ELLIOTT ; LI XIAODONG (US);
SENOLOGY INC (US); O'CONNELL SHAW) 22 August 2002 (2002-08-
22)

D2: WO 02/30981 A (PE CORP NY) 18 April 2002 (2002-04-18)

D3: GB-A-2 364 058 (SMITHKLINE BEECHAM PLC ; SMITHKLINE
BEECHAM CORP (US)) 16 January 2002 (2002-01-16)

Section IV

1. The IPEA agrees with the non-unity objection originally raised by the International Search Agency (ISA) (Rule 13 PCT). The only common inventive concept underlying present international application can be seen in the provision of variant T1R family taste receptors. However, taking into account that such receptors are taught in D1 (see Section V below) said common inventive concept no longer exists. Correspondingly present claims no longer relate to one invention, thus being in discordance to Rule 13.1 PCT. The opinion of this International examining Authority is that said international application relates to at least two separate inventions, namely:

invention 1: claims 4-5, 14, 17, 39, 67 (completely); claims 1-3, 20-38, 42-66,
70-72 (only partially)

Feline T1R taste receptor of SEQ ID No. 2 encoded by SEQ ID
No. 1 or SEQ ID No. 99 and the uses thereof

invention 2: claims 6, 16, 18, 41, 68 (completely); claims 1-3, 8-13, 20-38, 42-
66, 70-72 (only partially)

Feline T1R taste receptor of SEQ ID No. 61 encoded by SEQ ID
No. 59 or SEQ ID No. 60 and the uses thereof

invention 3: claims 7, 15, 19, 40, 69 (completely); claims 1-3, 8-13, 20-38, 42-66, 70-72 (only partially)

2. Section V

2.1 Document D1 discloses the human T1R3 taste receptor which is over 81,8% identical to present SEQ ID 1 and SEQ ID 99. Said human T1R3 taste receptor protein shares some 75% identical to the protein of SEQ ID No.2 of the present international application and is seen as a "variant" of the nucleic acid/polypeptide of present invention/group of inventions 1. Therefore, novelty and inventive step of claims 1-5, 8-14, 17, 20-39, 42-67, 70-72 of said invention 1 cannot be acknowledged (Article 33(2)(3) PCT).

3. Further comments

3.1 With respect to clarity of claims present application is open to objection under Article 6 PCT for the following reasons:

3.2 It is highly doubtful that a fragment of only 42 amino acids will have "substantially the same biological activity" as the full length protein.

3.3 Expressions like "substantially the same" are open to interpretation and are therefore unclear. Therefore claims containing such expressions are also unclear (Article 6 PCT).

3.4 Expressions like "biological activity" are unclear since no method of measurement has been indicated. Correspondingly, all claims containing this expression are also unclear (Article 6 PCT).

3.5 All claims containing the term "comprising" are unclear since it appears not possible to define the subject matter for which protection is sought (Article 6 PCT).